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EXAMINER

WORTMAN, DONNA C 8

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/060,941

Applicant(s)

DYALL ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on 29 January 2002.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-10, 26, 27, 55-64, 68 and 69 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 55-64, 68 and 69 is/are allowed.

6) ☒ Claim(s) 1, 3-10 and 26 is/are rejected.

7) ☒ Claim(s) 2 and 27 is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_.

Claims 11-25, 28-54, and 65-67 were canceled by preliminary amendment.

Claims 1-10, 26, 27, 55-64, 68 and 69 remain pending and under examination.

Claims 8, 9, 10, are objected to because of the following informalities:

In claim 8, the following misspellings:

in line 2, "syncytial"; in line 3, "hepatitis"; in line 5, "coxsackievirus". Also, in claim 8, "respiratory syncytia(l) virus" is recited twice.

In claim 9, the following misspellings:

in line 2, "syncytial"; in line 3, "hepatitis."

In claim 10, line 2, "syncytial" is misspelled.

In claim 62, the following misspellings:

in line 2, "syncytial"; in line 4, "hepatitis"; in line 6, "coxsackievirus". Also, in claim 62, "respiratory syncytia(l) virus" is recited twice.

In claim 63, the following misspellings:

in line 2, "syncytial"; in line 4, "hepatitis".

In claim 64, "syncytial" is misspelled.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite as it recites a method, further comprising a cell culture not containing a subgenomic viral replication system. It is not clear what steps of the method of claim 1, if any, are intended to be performed with or on the cell culture of claim 3, or whether the use of the cell culture in the method of claim 1 requires some additional, unrecited, process steps.

Claim 26 is indefinite as it rather confusingly recites "wherein the each viral replication system ...". It is possible that the use of term "the each" is inadvertent; if so, it is suggested that the word "the" should be omitted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0034732 A1, Capon et al. Capon describes a method for determining susceptibility to an HCV antiviral drug and susceptibility to an HCMV antiviral drug using various resistance test vectors, including replicons and defective genomes that are derived from patients infected with HCV and HCMV and introduced into host cells that anticipates the method instantly claimed. Since the claims do not distinguish over using two separate cell cultures either in parallel, or in any order, the subject matter is anticipated by Capon.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Capon et al., cited above. Although claim 3 is unclear, as discussed above, for the purposes of this examination it has been interpreted as reading on either the presence of a control cell culture, or of untransfected host cell cultures, both of which are necessarily present in the method of Capon, and therefore the subject matter of claim 3 is anticipated. Alternatively, because the use of controls is standard laboratory practice and would have been required in order to detect any toxicity of antiviral substances to the host cell itself, the presence of an additional cell culture would have been obvious over Capon et al.

Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capon et al., cited above, in view of US Patent No. 5,723,319 to King et al. Capon discusses the emergence of drug-resistant viral mutants in chronic infections with hepatitis B as well as hepatitis C viruses (see [0007], e.g.), but does not teach a subgenomic viral replication system for hepatitis B virus. King discloses a cultured cell line that inducibly expresses hepatitis B, and its use for testing for antiviral substances. It would have been obvious to one of ordinary skill in the art to have performed hepatitis B antiviral testing as taught by King in addition to the HBV and HCMV antiviral testing taught by Capon because Capon teaches that the existence of drug-resistant HBV is also important.

Claims 9, 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capon et al., cited above, in view of US Patent No. 6,270,958 to Olivo et al. Capon discusses the importance of antiviral screening for detection of drug resistance as discussed above but does not teach subgenomic viral replication system for such negative-strand RNA viruses as respiratory syncytial virus or Sindbis virus, e.g. Olivo et al. disclose subgenomic viral replication systems for a variety of negative strand viruses and their use for screening compounds for antiviral activity (col. 4, lines 7-11, e.g.). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed antiviral testing for negative strand RNA viruses as taught by Olivo in addition to the HBV and HCMV antiviral testing taught by Capon because both references teach the use of cell cultures comprising subgenomic viral replication systems for antiviral testing.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,168,915 to Scholl et al. discloses mixed cell cultures for detecting and differentiating viruses.

Claims 55-64, 68, and 69 are allowed.

Claims 2 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach combining a first cell culture comprising a first subgenomic viral replication system and a second cell culture comprising a second subgenomic viral replication system, wherein the first subgenomic viral replication system is genetically distinct from the second subgenomic viral replication system, or the mixed cell culture resulting from combining such cultures, for use in screening a candidate antiviral agent for antiviral activity as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'D. Wortman', with a long horizontal flourish extending to the right.

Donna C. Wortman, Ph.D.  
Primary Examiner  
Art Unit 1648

dcw  
March 21, 2003